

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
LAFAYETTE DIVISION

In re INOTIV, INC. SECURITIES
LITIGATION

Case No. 4:22-cv-00045-PPS-JEM

Judge Philip P. Simon
Magistrate Judge John E. Martin

**DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS
LEAD PLAINTIFF'S FIRST AMENDED CLASS ACTION COMPLAINT**

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ISSUE STATEMENT

Pursuant to Local Rule 7-1(e)(2)(B), Defendants state that issues raised in their motion to dismiss include:

1. Whether the First Amended Complaint for Violations of the Federal Securities Laws (“FAC”) (ECF No. 53) states a claim in accordance with the heightened pleading requirement imposed by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (“PSLRA”);
2. Whether the FAC adequately alleges an actionable and material omission regarding: (1) United States Department of Agriculture inspections, the Cumberland Facility, or any related issues; or (2) the grand jury subpoenas, the criminal investigation into importation of non-human primates, or any related issues;
3. Whether the FAC adequately alleges that Defendants made a materially false or misleading statement regarding: (1) Envigo’s business and research models; (2) the Cumberland Facility and related legal and regulatory events; or (3) non-human primates and Inotiv’s related business;
4. Whether Defendants can be held liable for statements they did not make;
5. Whether Defendants’ forward looking statements are protected by the PSLRA safe harbor;
6. Whether the FAC alleges facts giving rise to a strong inference of scienter;
7. Whether the FAC adequately alleges loss causation;
8. Whether the FAC states a claim under § 14(a) and adequately alleges a materially false or misleading proxy statement and loss causation; and
9. Whether Plaintiff states a claim for control person liability under § 20(a), which is contingent on a primary violation.

INTRODUCTION

The First Amended Class Action Complaint (“FAC”) mistakes quantity for quality. Despite its unnecessary length, Lead Plaintiff Oklahoma Police Pension and Retirement System’s (“Plaintiff”) entire 135-page FAC ignores Inotiv, Inc.’s (“Inotiv” or the “Company”) disclosures and instead rests on faulty fraud-by-hindsight allegations and the incorrect assumption that Inotiv was required to provide, in real-time, immaterial and already public information. That is not the law. Rather, the FAC contains the exact type of vague and ambiguous allegations (all rooted in hindsight) that the Private Securities Litigation Reform Act of 1995 (“PSLRA”) strictly forbids. 15 U.S.C. § 78u-4(b); *Tellabs, Inc. v. Makor Issues & Rts.*, 551 U.S. 308, 321 (2007).

Plaintiff alleges that nearly every single statement cited in the FAC was false or misleading because Inotiv and defendants Robert Leisure, Beth Taylor, John Sagartz, and Carmen Wilbourn (the “Individual Defendants” and, together with the Company, the “Defendants”) failed to disclose details relating to: (1) an unprofitable and financially immaterial facility in Cumberland, Virginia (“Cumberland Facility”) that was acquired in November 2021 through the acquisition of Envigo RMS Holding Corp. (“Envigo”); and (2) receipt of industry-wide grand jury subpoenas concerning a United States Attorney’s Office for the Southern District of Florida (“USAO-SDF”) investigation into the importation of non-human primates (“NHPs”). But, Plaintiff’s allegations fail to plausibly allege claims for violations of § 10(b), § 14(a), and § 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, because Plaintiff does not adequately allege a material misrepresentation or omission, fail to allege a strong inference of scienter, and fails to allege a plausible loss causation theory. Accordingly, the Court should dismiss the FAC, with prejudice.

First, the FAC fails to allege a fundamental element of both a § 10(b) and § 14(a) claim: a material misrepresentation or omission. None of the allegedly omitted information was required to be disclosed as a matter of law. Inotiv is subject to routine regulatory oversight and disclosed

that fact, as well as the potential for noncompliance. Moreover, both the purported conditions at the Cumberland Facility and the USAO-SDF investigation concerning importation of NHPs were public prior to the beginning of the class period. If that were not enough, the Company made repeated disclosures in its public filings regarding the risk of regulatory and governmental action and ongoing disruption to its supply of NHPs. Nor does Plaintiff plead a single fact that, even if true, would show that any statement made by Inotiv was false or misleading. Furthermore, many of the statements in the FAC are classic examples of puffery, statements of opinion, or forward-looking statements protected by the safe harbor, none of which are actionable.

Second, Plaintiff fails to adequately allege any inference of scienter, let alone a strong one in support of its securities fraud claim. Not a single classic indicator of fraud is alleged in the FAC—there are no contemporaneous internal reports or communications suggesting a plot to defraud investors; no witnesses who claim to have firsthand knowledge of wrongdoing; and no suspiciously timed insider stock sales. Similarly, Plaintiff does not and cannot allege that Inotiv knew that an industry-wide subpoena was part of an investigation that would eventually lead to the indictment of individuals at one of its suppliers. Notably, no employees from Inotiv or its subsidiaries were charged with any wrongdoing.

Third, Plaintiff's loss causation theory fails with respect to both its § 10(b) and § 14(a) claim. Inotiv's stock price movement is totally inconsistent with the allegation that fraud was disclosed through each of the purported corrective disclosures, many of which fail for the additional reason that they did not reveal new information. Further, Plaintiff cannot allege losses based on statements made after May 26, 2022, the date Plaintiff last purchased Inotiv stock.

While the FAC takes every opportunity to vilify Inotiv's business model and the practice of breeding research models for medical research and testing purposes, Plaintiff, a "sophisticated

institutional investor,” was undoubtedly well aware of (and presumably saw opportunity in) that business model when it made the decision to invest in Inotiv. Plaintiff further made the decision to *maintain* a portion of its investment as each of the inspection reports and declarations now quoted at length in the FAC were made public. In fact, a week after the U.S. Department of Justice (“DOJ”) filed a complaint against Envigo relating to the Cumberland Facility and a related TRO was issued, Plaintiff *purchased* more than 30,000 additional shares. (*See* ECF No. 53-1 at 3). Such purchases are fundamentally at odds with Plaintiff’s made-for-litigation argument that it was duped by Defendants’ alleged omissions regarding the Cumberland Facility.

In sum, the FAC is inadequately pled and filled with theories that, as a matter of law, cannot constitute claims under § 10(b) or § 14(a). Accordingly, Plaintiff’s § 20(a) control person liability claims, which are contingent on a primary violation, fail as well. For these reasons and those that follow, the FAC should be dismissed in its entirety, with prejudice.

BACKGROUND

Inotiv is an Indiana corporation headquartered in West Lafayette, Indiana, and a contract research organization (“CRO”) that specializes in the commercial production and sale of laboratory research models, principally purpose-bred rats and mice and large research models (NHPs and rabbits) for use by researchers, including pharmaceutical, chemical, and medical device companies. (¶ 5¹; Ex. E at 4, 9²). Inotiv focuses on support for the early phases of drug and device

¹ Unless otherwise noted, all ¶ citations herein are to the FAC. Additionally, all internal citations and quotations are omitted and all emphasis is added unless otherwise noted.

² All Exhibits referenced herein are attached to the Declaration of Carrie M. Stickel. “[D]ocuments attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to his claim,” and thus “may be considered by a district court in ruling on the motion to dismiss.” *Wright v. Associated Ins. Cos. Inc.*, 29 F.3d 1244, 1248 (7th Cir. 1994). Additionally, the Court may take judicial notice of matters of public record without converting a 12(b)(6) motion into a motion for summary judgment. *Palay v. United States*, 349 F.3d 418, 425 n.5 (7th Cir. 2003).

development, which include testing on live research models prior to human clinical trials, as required by the FDA and other regulators.³ (¶ 5; Ex. E at 9). Inotiv works only with research models where it is mandated by such legal or regulatory requirements or when there is no alternative method available. (Ex. AA at 1). Inotiv’s research models have played an integral role in the development of advanced pacemakers, as well as critical research into Parkinson’s disease and multiple sclerosis. (Ex. P at 1).

I. THE CUMBERLAND FACILITY

As part of its strategic acquisition plan, Inotiv began substantive discussions to acquire Envigo, a global provider of research models and services, in April 2021. (Ex. C at 15). Following a period of due diligence, negotiations, and shareholder approval, the stock and cash acquisition closed on November 5, 2021. (¶¶ 42-52). As a result, Inotiv acquired a new Research Models and Services (“RMS”) business segment (¶ 36), thereby becoming a full-spectrum preclinical solutions provider and a one-stop shop “for the entirety of discovery and nonclinical development.” (Ex. F at 9; *see also* Ex. I at 3; ¶ 35). Additionally and as is relevant here, through its acquisition of Envigo, Inotiv acquired a purpose-bred canine facility in Cumberland and an NHP facility in Alice, Texas. (¶ 110).

As Inotiv repeatedly disclosed, Envigo is subject to a variety of governmental regulations, including the Animal Welfare Act (“AWA”), which requires breeders and dealers to be licensed with the USDA. (¶¶ 53, 56). The USDA sets acceptable standards for regulated animals and monitors compliance through “inspections, enforcement, educations, and cooperative efforts.” (¶¶

³ The drug development process has five steps: (1) discovery and development; (2) preclinical research; (3) clinical research; (4) Federal Drug Administration (“FDA”) review; and (5) FDA post-market safety monitoring. (Ex. BB at 1-2). Inotiv provides products and services to customers at steps one and two. During step two, the drugs that make it through discovery and development undergo mandatory laboratory and animal testing to determine if they should be tested in people. (*Id.* at 3).

53, 56). The USDA conducts both routine inspections, which are periodic, unannounced general inspections, and focused inspections, which are unannounced inspections for a specific purpose. (¶ 57). At the end of each inspection, the assigned USDA inspector conducts an exit interview with a facility representative to summarize the inspection and any noncompliant items (“NCIs”) and provide the facility an “opportunity to present additional information that may influence the determination of compliance.” (Ex. Y at 5). If a facility provides information that “influences an NCI on the current version” of the report, the USDA inspector must modify the draft report to accurately reflect such information. (*Id.*). Accordingly, the inspection report and any findings are subject to change when an exit interview is conducted. (*See id.*). Even after an exit interview, the USDA continues to provide opportunities to correct any NCIs and provides for an appeal process if the facility disagrees with its findings. (¶ 58; Ex. Y at 7). Final inspection reports are later provided to the facility and made public on the USDA’s website. (*See* Ex. Y at 6; ¶ 196).

The USDA conducted five inspections of the Cumberland Facility between July 2021 and May 2022, the findings of which are all publicly available:

Inspection Date	Report Date	Number of NCIs
July 20-21, 2021	October 18, 2021	18
October 25, 2021	December 30, 2021	13
November 16, 2021	March 22, 2022	26
March 8, 2022	March 18, 2022	5
May 3, 2022	May 6, 2022	1

(¶¶ 61, 70, 77, 87, 91; Ex. Z at 1, 15, 29, 44, 66, 73). As alleged in the FAC, reports for the July and October inspections were ***published on the USDA’s website on November 15, 2021, and January 28, 2022***, respectively, so Plaintiff and the putative class were fully aware of such facts when making subsequent investment decisions. (¶¶ 196, 210; *see* ECF No. 53-1 at 3). Following the initial July 2021 inspection, Envigo appealed certain findings and began to remediate other findings, some of which required significant capital improvements. (¶ 217; Ex. G at 7). In its 2021

Form 10-K filed December 21, 2021—the first periodic SEC filing following the acquisition of Envigo—Inotiv disclosed that “[d]uring the period from July through December 2021, one of the Envigo’s U.S. facilities was inspected on several occasions by the USDA. Following the inspection, USDA issued inspection reports with findings of non-compliance with certain USDA laws and regulations.” (Ex. G at 7). Inotiv further stated that Envigo had formally appealed certain findings and that the USDA “indicated it intends to conduct a formal investigation.” (*Id.*). Inotiv also warned that the “inspections and/or the investigation could lead to enforcement actions resulting in penalties that could include a temporary restraining order or injunction, civil and/or criminal penalties, and/or license suspension or revocation.” (*Id.*).

Despite Envigo’s remediation efforts, which are reflected by the diminishing number of NCIs in the preceding chart, government agents executed a search and seizure at the Cumberland Facility on May 18, 2022. (¶ 96). On May 19, 2022, the DOJ, which shares enforcement authority over the AWA, filed a civil Complaint for Declaratory and Injunctive Relief and an *ex parte* motion for a TRO against Envigo, which the Western District of Virginia granted on May 21, 2022. (¶ 98). Inotiv promptly disclosed the search and seizure, along with the filing of the civil action, on May 20, 2022. (Ex. L at 2).

Ultimately, on June 13, 2022, Inotiv announced that it had made the decision to close the Cumberland Facility and would implement an orderly closure plan, saying that “Inotiv has been pleased with the continued and significant progress in improvements at the Cumberland facility since the acquisition, as evidenced by recent inspections by the USDA,” but “[t]he required investments to improve the facility and the lead time to achieve these improvements have recently increased.” (Ex. M at 4; ¶ 109). Inotiv also noted that “Cumberland comprises less than 1% of our total Inotiv revenue and has not contributed to profits in our [RMS] segment since the acquisition”

and its closure would not “impact the Company’s financial guidance for fiscal year 2022.” (Ex. M at 4).⁴ Following the announcement, Inotiv’s stock price declined by a mere \$0.25 and then rebounded the following day. (¶ 263; Ex. X at 8).

On July 15, 2022, the court approved a settlement between Envigo, the DOJ, and the USDA, which resolved all civil and administrative complaints related to the Cumberland Facility. (Ex. N at 2; ¶ 238). Critically, the settlement did not require Envigo to pay any fines or penalties or admit liability or wrongdoing. (Ex. N at 2). The settlement also acknowledged that Envigo and the DOJ had agreed to a plan to safely, efficiently, and humanely transfer the dogs from the facility. (*Id.*). Thereafter, and once the transfer plan was successfully implemented and concluded, the court dismissed the case against Envigo with prejudice. (*Id.*).

II. ORIENT BIO RESOURCE CENTER

Continuing its strategic acquisition plan, on January 27, 2022, Inotiv acquired Orient Bio Resource Center (“OBRC”), an importer of NHPs for research and a primate quarantine and holding facility also located in Alice, Texas. (¶¶ 1, 38; Ex. H at 8). Inotiv’s acquisition of OBRC allowed Inotiv to “provide increased access to critical research models” and expand “facilities necessary for the development of safe and effective medicine.” (Ex. H at 8). However, at some point prior to June 2019, the USAO-SDF opened an investigation into the importation of NHPs. (¶ 112). That investigation was made public in June 2021, when the USAO-SDF unsealed a criminal proceeding against a former OBRC executive⁵ who then pled guilty to making a false statement to government agents on August 4, 2021. (¶ 114). Additionally, in June 2021, before

⁴ Market commentary about the decision was positive. One analyst commented that it believed the decision “[would] ultimately support stronger EBITDA margins” and “expect[ed] operations to be more efficient given the consolidation into recently refurbished facilities.” (Ex. V at 1).

⁵ As the FAC acknowledges, this former executive departed OBRC upon the closing of Inotiv’s acquisition. (¶ 128).

Inotiv's acquisitions, Envigo and OBRC, as well as other unrelated CROs, received grand jury subpoenas seeking the production of documents relating to the procurement of NHPs from foreign suppliers. (¶ 116; Ex. I at 4; Ex. K at 3; Ex. U at 2). While receipt of a subpoena, without more, is not material or otherwise required to be disclosed under applicable law, Inotiv nevertheless publicly disclosed the Envigo and OBRC subpoenas on February 16 and May 16, 2022, respectively. (Ex. I at 4; Ex. K at 3). Subsequently, on November 16, 2022, the USAO-SDF publicly announced that the government had charged eight individuals, including employees from the principal supplier of NHPs to Inotiv, with felonies for their alleged roles in bringing wild-caught NHPs into the United States from December 2017 through January 2022. (¶ 117). The following day, November 17, 2022, Inotiv filed an 8-K disclosing the charges to its supplier. (Ex. O at 2).

III. INOTIV DISCLOSED ALL RELEVANT RISKS.

Prior to and throughout the Class Period, Inotiv made appropriate disclosures regarding business and regulatory risks. Among other things, Inotiv disclosed that: (a) its animal research facilities are subject to laws and government regulations, including the AWA and USDA, and any “failure by [Inotiv] to comply with existing regulations could harm [its] reputation and operating results” (*see* Ex. A⁶ at 5; Ex. B at 6, 9; Ex. E at 7; Ex. G at 3, 6-7); (b) it was subject to USDA inspections and the USDA could “impose fines, suspend and/or revoke animal research licenses or confiscate research animals” (Ex. A at 4); and (c) it faced risks relating to the supply of NHPs and “depends on a limited international source of supply for certain products, such as non-human primates,” and that supply has been and would likely continue to be disrupted (Ex. B at 7; *see also*

⁶ Inotiv was formerly known as Bioanalytical Systems, Inc. (¶ 6). For this reason, Bioanalytical Systems, Inc. is listed as the registrant on the December 22, 2020 Form 10-K, attached hereto as Exhibit A.

Ex. E at 6; Ex. G at 5, 8). In short, relevant risks related to USDA inspections and findings and the supply of NHPs were well documented before both acquisitions closed.

IV. INVESTORS REFLEXIVELY FILE SUIT.

This class action lawsuit was reflexively filed on June 23, 2022, following Inotiv's announcement that it would close the Cumberland Facility. (ECF No. 1). Five months later, on November 14, 2022, Plaintiff filed an amended complaint that asserted the same claims based on Defendants' disclosures regarding the Cumberland Facility, and added a claim under Section 14(a) of the Exchange Act, as well as two additional Individual Defendants. (ECF No. 52). The following week, Plaintiff amended again, filing the FAC in response to Inotiv's truthful and timely disclosures regarding the USAO-SDF proceeding. (ECF No. 53). The FAC extended the class period to September 21, 2021 through November 16, 2022, and further alleged false and misleading statements and material omissions concerning Inotiv's NHP business. (*Id.*). Despite filing multiple complaints and adding an additional theory of liability, Plaintiff still fails to adequately state a claim for securities fraud, as discussed below.

LEGAL STANDARDS

To state a claim for securities fraud under Section 10(b) of the Exchange Act and SEC Rule 10b-5, a plaintiff must adequately allege each of the following: (1) a material misrepresentation or omission; (2) scienter; (3) a connection to the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Stoneridge Inv. Partners LLC v. Scientific-Atlanta*, 552 U.S. 148, 157 (2008). On the other hand, to state a claim under Section 14(a), a plaintiff must allege: (1) that the proxy statement contained a material misstatement or omission that (2) caused the plaintiff's injury, and (3) that the proxy solicitation was an essential link in accomplishing the transaction. *Kuebler v. Vectren Corp.*, 13 F.4th 631, 637 (7th Cir. 2021).

In pleading these elements, plaintiffs must generally satisfy both Rule 9(b) of the Federal Rules of Civil Procedure and the heightened-pleading requirements of the PSLRA. Fed. R. Civ. P. 9(b); 15 U.S.C. § 78u-4(b); *Tellabs*, 551 U.S. at 321; *Kuebler*, 13 F.4th at 638 (“the PSLRA imposes heightened pleading requirements on Section 14(a) plaintiffs”). Rule 9(b) requires a plaintiff to state the circumstances constituting the fraud “with particularity.” Fed. R. Civ. P. 9(b). “This ordinarily requires describing the ‘who, what, when, where, and how’ of the fraud.” *Cornielsen v. Infinium Cap. Holdings, LLC*, 168 F. Supp. 3d 1033, 1040 (N.D. Ill. 2016). The PSLRA contains additional, “[e]xacting pleading requirements,” as a “check against abusive litigation by private parties” and “to screen out frivolous suits.” *Tellabs*, 551 U.S. at 313, 324. Under the PSLRA, a plaintiff must “specify each statement alleged to have been [materially] misleading” and “the reason or reasons why the statement is misleading.” *Id.* at 321; 15 U.S.C. § 78u-4(b)(1). In addition, for the Rule 10b-5 claim, for each alleged material omission or false or misleading statement, a plaintiff must “state with particularity *facts* giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A); *Pugh v. Tribune Co.*, 521 F.3d 686, 693 (7th Cir. 2008). And where, as here, “an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1)(B); *Cornielsen*, 168 F. Supp. 3d at 1041.

ARGUMENT

The Amended Complaint fails to the pleading standard under Rule 9(b), let alone the PSLRA’s heightened requirements. Specifically, Plaintiff has failed to plead adequately an actionable false or misleading statement, materiality, scienter, or loss causation in support of its § 10(b) claim. Similarly, Plaintiff fails to allege a materially false or misleading proxy statement or loss causation in support of its § 14(a) claim. Plaintiff’s § 20(a) claims, therefore, fail as well.

I. THE ALLEGEDLY OMITTED INFORMATION WAS NOT REQUIRED TO BE DISCLOSED, BUT WAS NEVERTHELESS.

Plaintiff's FAC relies almost exclusively on the failure to disclose allegedly omitted information. However, issuers "are entitled to keep silent (about good news as well as bad news) unless positive law creates a duty to disclose." *Gallagher v. Abbott Lab'ys*, 269 F.3d 806, 808 (7th Cir. 2001). Absent such a duty, disclosure is required only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading. *Anderson v. Abbott Lab'ys*, 140 F. Supp. 2d 894, 903 (N.D. Ill.), *aff'd sub nom.*, 269 F.3d 806 (7th Cir. 2001). "Merely mentioning a topic, however, does not require the company to disclose every tangentially related fact that might interest investors." *Id.* Despite Plaintiff's assertions, neither Regulation S-K⁷ nor any other positive law required disclosure of the purportedly omitted information, which Inotiv nevertheless disclosed. Further, Defendants did not make any affirmative statements that were rendered materially false or misleading due to the purported omissions, as discussed below.

⁷ Items 303, 103, and 105 of SEC Regulation S-K also do not provide a duty to disclose the allegedly omitted information. As an initial matter, the required information under Regulation S-K was disclosed. (*See ¶ 255; see Section I, B; see also Nurlybayev v. ZTO Express (Cayman) Inc.*, No. 17 CV 6130-LTS-SN, 2019 WL 3219451, at *7 (S.D.N.Y. July 17, 2019) (there can be no Item 303 liability for *disclosed* uncertainties). Item 103 only requires an issuer to disclose material "proceedings known to be contemplated by government authorities" and which are not "ordinary routine litigation incidental to the business." 17 C.F.R. § 229.103; *W. Palm Beach Firefighters' Pension Fund v. Conagra Brands, Inc.*, 495 F. Supp. 3d 622, 646-47 (N.D. Ill. 2020), *aff'd sub nom. Nat'l Elevator Indus. Pension Fund v. Conagra Brands, Inc.*, No. 21-1155, 2022 WL 1449184 (7th Cir. May 9, 2022) (requiring "actual knowledge"). With respect to materiality, neither the USDA inspections nor the DOJ lawsuit sought any fines, penalties, or other damages and, as discussed below, the Cumberland Facility was not profitable and its closure had a *positive* financial impact. *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 12 (S.D.N.Y. 2016) (Wells notices and SEC subpoenas did not give rise to a duty to disclose and investigation was not material where there was "no allegation that the possibility of an injunction would have a material effect on [the issuer's] assets"). No proceeding has ever been filed against the Company relating to the NHP investigation, nor does the FAC allege that one was contemplated, let alone a material one. Further, the FAC fails to allege an inference of scienter, let alone actual knowledge. (*See Section VI*). Finally, the Seventh Circuit has not confirmed whether Regulation S-K imposes a duty to disclose that, when violated, can give rise to fraud under the Exchange Act. Various other circuits have held that it does not. *See, e.g., Oran v. Stafford*, 226 F.3d 275 (3rd Cir. 2000) (Alito, J.).

A. Defendants Had No Duty to Disclose the Allegedly Omitted Information.

Plaintiff contends that nearly every statement identified in the FAC was false or misleading based on the omission of information about the USDA inspections, the grand jury subpoenas, and/or the USAO-SDF investigation into the importation of NHPs. (*See, e.g., ¶¶ 171, 202, 205*) However, courts in this Circuit and around the country have long held that the federal securities laws do obligate issuers to disclose government investigations or contested, uncharged, or unadjudicated claims of wrongdoing, let alone a subpoena received as part of an inquiry into an unrelated entity. *Société Générale Sec. Servs., GbmH v. Caterpillar, Inc.*, 17 CV 1713, 2018 WL 4616356, at *5 (N.D. Ill. Sept. 26, 2018) (no duty to disclose ongoing IRS investigation or cooperation with a grand jury subpoena); *Heavy & Gen. Laborers' Loc. 472 & 172 Pension and Annuity Funds v. Fifth Third Bancorp*, 20 C 2176, 2022 WL 1642221, at *15 (N.D. Ill. May 24, 2022) (no duty to disclose a CFPB investigation or the fact that defendants "participated in the investigation by providing information and documents and identifying unauthorized activity," despite statements about regulatory compliance during class period); *In re Lions Gate*, 165 F. Supp. 3d at 12 ("a government investigation, without more, does not trigger a generalized duty to disclose"). Accordingly, as a matter of law, Inotiv had no duty to disclose any of the allegedly omitted information on which Plaintiff bases its claims.

B. Nevertheless, Inotiv Disclosed the Allegedly Omitted Information.

Moreover, with respect to the USDA inspections and findings, Inotiv specifically cautioned investors prior to and after the acquisition that "Envigo is subject to a variety of governmental regulations," "expends significant resources on compliance efforts," its facilities are "subject to routine formal inspections by regulatory and supervisory authorities," including the USDA, and "[f]ailure to comply with applicable governmental regulations could harm [its] business." (Ex. D at 7; *see also* Ex. A at 5; Ex. B at 6, 9; Ex. E at 7; Ex. G at 3, 6-7). Inotiv, therefore, acknowledged

the potential for noncompliance and was not required to disclose more. *See Anderson*, 140 F. Supp. 2d at 906 (FDA inspections and findings were not material due to the “repeating cycle of inspections, findings and negotiations, without any FDA sanctions”); *Singh v. Cigna Corp.*, 918 F.3d 57, 64 (2d Cir. 2019) (disclosure noting complexity of regulatory framework and significant resources allocated to compliance suggested “caution (rather than confidence) regarding the extent of [defendant’s] compliance.”). Moreover, the USDA reports themselves were made public shortly after they were finalized—indeed, the first reports were posted on the USDA’s website as early as November 15, 2021. (¶ 196). Further, once the USDA investigation progressed from routine inspections to the execution of a warrant and filing of a civil case against Envigo, Inotiv promptly disclosed as much. (Ex. L at 2).⁸

Similarly, prior to the Envigo acquisition and throughout the class period, Inotiv warned investors that “Envigo depends on a limited international source of supply for certain products, such as non-human primates,” “[a]ny disruption of supply could harm [its] business,” and “our supply of these NHPs was and continues to be disrupted,” which “has impacted our ability to fill our customer’s orders.” (Ex. D at 5-6; *see also* Ex. B at 7; Ex. E at 6; Ex. G at 5, 8). This is the exact risk that materialized in connection with the NHP investigation, and which Plaintiff incorrectly alleges was omitted. (¶ 227). Relatedly, as Plaintiff admits, the USAO-SDF investigation was “a matter of public record since as early as June 22, 2021,” (¶¶ 113-14) long before either acquisition. *Higginbotham v. Baxter Int’l, Inc.*, 495 F.3d 753, 759 (7th Cir. 2007) (“The securities laws do not require firms to ‘disclose’ information that is already in the public

⁸ Additionally, Plaintiff acknowledges that the Cumberland Facility was the subject of activist scrutiny and public reports criticizing purported conditions as early as July 2019 and continuing throughout the class period. (¶¶ 146-152, 193). Even if poor conditions at the Cumberland Facility were somehow material to an investment in Inotiv, which it was not (*see* Section V), such information was already in the public domain and is not required to be disclosed. *See Higginbotham*, 495 F.3d at 759 (“The securities laws do not require firms to ‘disclose’ information that is already in the public domain.”).

domain.”). Finally, Inotiv disclosed the grand jury subpoenas on February 16 and May 16, 2022, and as soon as Inotiv received news that the USAO-SDF had indicted employees of its supplier, that news was promptly disclosed, despite the fact that no employees from Inotiv or its subsidiaries were charged with any wrongdoing. Accordingly, any suggestion that the allegedly omitted information was not disclosed is directly contradicted by the FAC.

II. THE CONFIDENTIAL WITNESSES AND HSUS REPORT DO NOT SUPPORT PLAINTIFF’S ALLEGATIONS OF FALSITY.

Lacking any direct evidence that Defendants’ statements were false or misleading when made, Plaintiff points to vague allegations from four confidential witnesses (“CWs”) and a purported employee’s statement in a report from HSUS, an activist organization. (¶¶ 121-145, 158). These allegations are likewise insufficient under the PSLRA and cannot establish the falsity of Defendants’ statements.

While Plaintiff is not necessarily required to disclose the identity of the CWs or employee in the HSUS report, Plaintiff must “describe [its] sources with sufficient detail to support the probability that a person in the position occupied by the source would possess the information alleged, or in the alternative provide other evidence to support [its] allegations.” *Boca Raton Firefighters’ & Police Pension Fund v. DeVry Inc.*, No. 10 C 7031, 2012 WL 1030474, at *3 (N.D. Ill. Mar. 27, 2012). Plaintiff wholly fails to do so here. For instance, absolutely nothing is alleged about the “Inotiv employee” referenced in the HSUS report. (See ¶ 158). Similarly, the minimal information alleged about the roles and responsibilities of the four CWs does not support an inference that each CW would possess the information alleged. Notably, none of the CWs were present during the due diligence tour of the Cumberland Facility, and there are no allegations that the conditions, the grand jury subpoenas, or anything else to do with the NHP business were discussed with any of the Individual Defendants. Further, none of the CWs are alleged to have

worked full-time at the Cumberland Facility or either of the Alice, Texas facilities. To the contrary, CW2, CW3, and CW4 were based in completely different states. (¶¶ 129, 133, 143). Only *one* CW is alleged to have had direct interaction alleged with any of the Individual Defendants and that interaction was related to the Envigo St. Louis site and completely unrelated to the alleged fraud. (¶ 130).

If that were not enough, no time frame whatsoever is provided for the purported employee's statement or observations referenced in the HSUS report. *DeVry Inc.*, 2012 WL 1030474, at *4 (“General and/or vague allegations about the company’s practices are insufficient because we cannot adequately assess their reliability.”); (*see* ¶ 158). CW3 is only alleged to have visited the Cumberland Facility for four days in March 2021, prior to the class period. (¶ 134). CW1 similarly fails to allege when he or she visited the Cumberland Facility and only alleges that there was an awareness of the NHP investigation “starting in approximately early 2019-2020”—well before the class period. (¶¶ 122, 127)⁹; *see City of Sunrise Firefighters’ Pension Fund v. Oracle Corp.*, No. 18-CV-04844-BLF, 2019 WL 6877195, at *14 (N.D. Cal. Dec. 17, 2019) (“CW accounts must be ‘contemporaneous’ with the alleged misstatements . . . because [the] ‘statement or omission must be shown to have been false or misleading *when made.*’”). Such allegations fall well short of alleging falsity under the PSLRA.

III. THE ALLEGED OMISSIONS DID NOT RENDER ANY STATEMENT FALSE OR MISLEADING.

The statements that Plaintiff alleges were rendered false or misleading as a result of the alleged omissions¹⁰ fall into three general categories—(1) statements about the quality and reach

⁹ Worse yet, CW2 and CW4 are only alleged to have second-hand knowledge of the Cumberland Facility. (¶¶ 132, 144-45).

¹⁰ The FAC alleges that every single statement was false or misleading based on an omission and fails to clearly allege which statements, if any, Plaintiff believes constituted a materially false statement on its face. The statements that Plaintiff appears to allege were false or misleading are also addressed below.

of Envigo's business and research models, as well as its compliance, (2) statements about the Cumberland Facility, the USDA's findings, and related remediation, and (3) statements about NHPs and Inotiv's related business. The FAC fails with respect to each category, as discussed below.

A. Defendants' Statements about Envigo's Quality and Compliance Did Not Omit Material Information.

Plaintiff claims that representations about the quality and reach of Envigo's business and research models, such as Inotiv "see[s] Envigo is a best-in-class provider of high-quality research models and services" and "Envigo has strategically positioned itself as a leader in research models services in key research locations" were false and misleading. (¶¶ 162, 167; *see also* ¶¶ 163-66, 171, 173, 175-77, 181-82, 200-02, 218, 220). But the FAC fails to allege any facts supporting that conclusion, let alone particularized, contemporaneous facts. Instead, Plaintiff claims such statements were misleading because Defendants failed to disclose: (a) that the Cumberland Facility beagles were purportedly viewed as "low quality" and "suck[ed]" according to an April 2022 HSUS activist report and CW1, (b) the USDA inspection findings, (c) the May 2022 search and seizure, and (d) the June 2021 Envigo subpoena. Notably, the USDA findings, DOJ search and seizure, and the subpoenas were promptly disclosed, and the allegations in the HSUS report are not pled with sufficient particularity, as discussed above. Moreover, many of these statements are immaterial puffery or nonactionable opinions, as discussed below.

Further, purportedly omitted information about the Cumberland Facility—a small part of Envigo's business—does not render generalized statements about the high-quality nature of Envigo's research models and business, as a whole, false or misleading. (*See* ¶¶ 162-67, 171, 173, 175-77, 181-82, 200-02, 218, 220); *see In re Supreme Indus., Inc. Sec. Litig.*, 3:17-CV-143-PPS/MGG, 2019 WL 1436022, at *3 (N.D. Ind. Mar. 29, 2019) ("Omitting one detail—even a

significant one—doesn’t render the whole story inaccurate or misleading.”); *DeVry Inc.*, 2012 WL 1030474, at *4 (“Even concrete allegations of wrongdoing may be deficient if they do not allege a problem of sufficient magnitude to undermine the defendants’ public statements about [defendant’s] policies and practices.”). Similarly, Plaintiff challenges the statement that “Envigo expends significant resources on compliance efforts,” but never alleges that Envigo did not, in fact, expend such resources. (¶¶ 175, 177). And “[a] company can both believe in and internally monitor its compliance [] and be the object of a[n] investigation, even one targeted at the very [subject] of that compliance.” *City of Austin Police Ret. System v. ITT Educ. Servs., Inc.*, 388 F. Supp. 2d 932, 946 (S.D. Ind. 2005).¹¹

Statements in the Merger Agreement discussing Envigo’s compliance with applicable law and regulatory standards similarly fail, despite Plaintiff’s assertion that they failed to disclose USDA violations and the USAO-SDF subpoena. (¶¶ 169, 171c). As an initial matter, these representations were made by Envigo, not any of the Defendants, prior to the acquisition. (See Ex. C at 9-12). It is black letter law that defendants “cannot be held liable for the warranty representations made [] by the opposing party in an arms-length business transaction before the merger took effect.”¹² *Forman v. Meridian Bioscience, Inc.*, 367 F. Supp. 3d 674, 680 (S.D. Ohio

¹¹ Plaintiff’s attack on the September 21, 2021 representation that Envigo “supplies customers with genetically consistent research models time after time” fares no better. (¶¶ 168, 171). Plaintiff makes no attempt to allege that customers were actually supplied anything but genetically consistent research models. While CW3 purportedly stated that customers “would not purchase dogs from the Cumberland Facility because of issues with ‘wet paw,’” a genetic abnormality, even if true, that allegation only confirms that customers did not receive (because they purportedly would not accept) research models with “wet paw.” (¶ 138). Further, Plaintiff fails to explain how omission of the USDA’s later findings regarding record maintenance could have possibly rendered the “genetically consistent” statement false or misleading. (¶ 171).

¹² Plaintiff does not allege that Wilbourn, the only defendant who was an employee of Envigo at the time the representation was made, had any involvement in or was otherwise responsible for representations in the Merger Agreement and similarly cannot be held liable for them. Similarly, one of the statements made during the September 2021 investor presentation was made by Hardy, the then-CEO of Envigo, which had not yet been acquired by Inotiv. (¶ 164). Defendants similarly cannot be held liable for this statement as a

2019), *on reconsideration*, 387 F. Supp. 3d 791 (S.D. Ohio 2019); *see also Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011). Even so, both of the representations at issue explicitly carved out matters set forth on the disclosure schedules, which Plaintiff acknowledges were not attached to the Form 8-K. (¶ 169). And the representation that Envigo was not “in violation in any material respect of any applicable Legal Requirement” explicitly carved out violations that “would not be material to [Envigo] and its Subsidiaries, taken as a whole,” which Plaintiff conveniently omits. (¶ 169; Ex. C at 11). As discussed below, the Cumberland Facility was not material. (*See Section V, B*). Further, the government has never asserted nor found that Envigo or Inotiv engaged in any wrongdoing with respect to the importation of NHPs and Plaintiff does not allege otherwise.¹³

Finally, if that were not enough to dismiss these allegations, the allegedly omitted information significantly *post-dates* many of the challenged statements. For example, Plaintiff relies on USDA inspection reports from October 18, 2021, December 30, 2021, and March 22, 2022, and documentation from the May 2022 search and seizure to allege the falsity of statements

matter of law, even if it were otherwise actionable, which it is not. *See Tracinda Corp. v. DaimlerChrysler AG*, 364 F. Supp. 2d 362, 395 (D. Del. 2005), *aff'd*, 502 F.3d 212 (3d Cir. 2007) (defendants could not be held liable for statements made by chairman of acquisition target before the acquisition closed). Finally, Plaintiff alleges that statements made in an analyst report were false or misleading. (¶¶ 170-71). Defendants cannot be held liable for those statements or any other statements they did not make. *See Janus*, 564 U.S. at 142-43.

¹³ Plaintiff's challenge to the representation that the Board “[took] into account the results of Inotiv's due diligence review of Envigo” when deciding whether to approve the Merger Agreement also fails. (¶¶ 174, 178). The FAC does not contain a single allegation that Inotiv disregarded or ignored its due diligence findings or any particularized allegations about the “material context” of what was allegedly uncovered in due diligence. (*See, e.g.*, ¶¶ 171, 177); *Conagra*, 495 F. Supp. 3d at 644 (after the fact assessment of what due diligence would have shown was not sufficient to support claim that earlier statements were misleading when made).

made on September 21, 2021 and October 5, 2021. (*See ¶¶ 171, 177*).¹⁴ Such allegations wholly fail to satisfy the PSLRA.

B. Defendants’ Statements about the Cumberland Facility Did Not Omit Material Information.

Plaintiff next asserts that various statements about the Cumberland Facility addressing the USDA’s findings and the Company’s related remedial actions were false or misleading, principally because Defendants allegedly failed to disclose that violations were ongoing. (*See, e.g., ¶¶ 198, 213-14*). However, none of these statements even so much as suggested that all the USDA’s findings had been fixed and many of them expressly acknowledged the opposite—that improvements were underway or ongoing, but would take time to fix. Accordingly, and as discussed below, none of these statements can support a claim.

Specifically, Plaintiff alleges that representations regarding improvements to the Cumberland Facility and the Company’s commitment to animal welfare made on November 11 and 16, 2021 and during Wilbourn’s February 3, 2022 Virginia congressional testimony, as well as the February 16, 2022 Form 10-Q, which repeated the 2021 Form 10-K disclosure regarding the USDA inspections and “findings of non-compliance,” were false and misleading because the statements failed to disclose various USDA inspection findings, conditions observed during the May 2022 search and seizure, and/or that violations persisted. (¶¶ 193-95, 197-98, 207-215, 217, 220-21; *see also ¶ 171*).¹⁵ Once again, Plaintiff attempts to plead fraud by hindsight by relying on

¹⁴ Although the statements from the November 5, 2021 Press Release, November 16, 2021 Presentation to the Jefferies London Healthcare Virtual Conference, and Q1 2022 Form 10-Q were made following the receipt of the July USDA inspection report on October 18 (¶¶ 171, 181, 201, 218), Plaintiff still impermissibly relies on subsequent USDA inspection findings, including the October 2021 inspection report which was not released until December 30, 2021, an April 2022 description of the beagles, and the May 2022 search and seizure. (¶¶ 171, 182, 202, 220).

¹⁵ Plaintiff’s allegation that the dogs were low quality based on the HSUS report (¶¶ 157-58, 171a) and statements from CW1 fails for the same reasons discussed above.

later-issued reports to prove the falsity of earlier statements. For example, Plaintiff alleges that the November 16 statement omitted the USDA's findings from the October and November 2021 inspections. (¶ 198). However, as discussed above, reports for those inspections were not issued until December 30, 2021 and March 22, 2022, and were subject to change until then.¹⁶ (*See Background*); *Abbott Lab'ys*, 269 F.3d at 808 (“Unless Abbott had a time machine, it could not have described on March 9 a letter that had yet to be written.”).

Even setting this insurmountable flaw aside, Plaintiff fails to specify how the statements¹⁷ were rendered false or misleading by the alleged omissions. None of these statements so much as suggested that all of the issues had been cured. To the contrary, each statement acknowledged that remediation was ongoing, and thus cannot have possibly omitted such information. Both the November 11 and 16 statements expressly acknowledged that Envigo had “recently participated in two separate USDA inspections” and was incorporating feedback from those inspections. (¶¶ 193, 197). Similarly, Wilbourn testified that Envigo was “working hard to fix the *current issues*,” “many of the corrective actions take [] several months to implement,” and that the October inspection report “still identified problems that had not been fully addressed.” (¶ 210; *see also* ¶ 208).¹⁸ The February 16, 2022 Form 10-Q similarly stated that the USDA had “issued inspection

¹⁶ Similarly, Plaintiff impermissibly claims that the November 2021 inspection findings, which had not yet been issued, and the March 2022 inspection and the May 2022 search and seizure, which had not yet occurred, render Wilbourn’s February 3, 2022 testimony and the February 16, 2022 disclosure false. (¶¶ 213-14, 221).

¹⁷ Such statements include, “[w]e are incorporating the feedback from these visits into operational enhancements already underway” (¶ 193); “we have launched an investigation to assess whether any improper actions occurred within the facility” (¶¶ 193-94); “are continuing to take the necessary corrective actions for all issues outline in the reports” (¶ 197); “invested more than \$3 million . . . in extensive upgrades and facility improvements to our Cumberland location” (¶ 197); and the “highest quality of animal welfare is a core value of our company” (¶ 197).

¹⁸ Plaintiff also challenges Wilbourn’s characterization of the issues as “temporary lapses” (¶¶ 209, 212), but that characterization cannot have possibly misled a reasonable investor given her contemporaneous statements about ongoing remediation. Plaintiff does not and cannot allege that Inotiv was not in fact taking steps to remediate the findings. Indeed, Wilbourn’s statement that the facility “showed improvement” (¶

reports with findings of non-compliance,” and “intend[ed] to conduct a formal investigation,” which “could lead to enforcement action resulting in penalties.” (¶ 217). Additionally, the November 16 statement, Wilbourn’s congressional statements, and the Q1 2022 Form 10-Q disclosure were made after the USDA published full inspection reports on its website and were a matter of public knowledge. (¶ 196); *See Higginbotham*, 495 F.3d at 759. In conclusion, the FAC fails to allege that any statements about the Cumberland Facility or remediation of issues there were false or misleading.

C. Defendants’ Statements About NHPs Did Not Omit Material Information.

Plaintiff next challenges statements about NHPs and the Company’s related business,¹⁹ alleging that these statements were false and misleading because they failed to disclose the June 2021 subpoenas to Envigo and/or OBRC, that the Company’s primary supplier of NHPs was the subject of an ongoing federal investigation, and, with respect to disclosures after the acquisition of OBRC, that it was a purported co-conspirator.²⁰ (¶¶ 187-90, 200-05, 219, 222, 224, 226-30, 232-33, 235-36; *see also* ¶ 171). As an initial matter and as discussed above in Section I, A, Inotiv had no duty to disclose the subpoenas or the criminal matter, even though each was disclosed, or any unadjudicated wrongdoing. Moreover, the FAC does not contain a single shred of contemporaneous evidence showing that Inotiv’s supplier was the subject of the investigation, let

210) is supported by the reports. The December 20, 2021 report from the October inspection showed only 11 repeat violations, out of 18 total violations noted in the reports from the July inspection. (*See* Ex. Z at 29-42).

¹⁹ Such statements include: Envigo’s ability to provide “quality” NHPs given Envigo’s position as “the world’s largest and most trusted sources of NHPs” (¶ 187); calling Envigo a “leader in primate welfare and supply” and stating that the OBRC acquisition “will provide increased access to critical research models and expanded facilities” (¶ 204); and disclosures regarding the grand jury subpoenas relating to the NHP federal investigation (¶¶ 219, 229; *see also* ¶¶ 188-89, 200-01, 224, 235 (alleging similar statements)).

²⁰ The FAC contradicts itself in this regard—admitting that OBRC has not been charged with any wrongdoing and referring to OBRC as a “potential” co-conspirator multiple times. (¶¶ 3 (“it was *likely* that OBRC was a co-conspirator”), 30, 119, 241).

alone that Defendants possessed such information when the statements were made. The FAC also conveniently omits that Inotiv's stock price rose, not fell, following its May 16, 2022 disclosure of the subpoena to OBRC, meaning Plaintiff cannot prove that it suffered any losses as a result of the alleged omission of the OBRC subpoena. (*See* Section VII).²¹

Even setting the preceding failures aside, none of the statements at issue, which discussed the RMS business generally (¶¶ 200, 224), NHPs (¶¶ 187-89), supply issues (¶¶ 201, 224, 232), and the subpoenas (¶¶ 219, 229, 235), were rendered false as a result of the alleged omissions. NHP supply risks were well documented throughout the class period and the USAO-SDF investigation was a matter of public record before the start of the class period. (¶¶ 113-14, 201; Ex. B at 7; Ex. D at 5-6, Ex. E at 6; Ex. Q at 4); *Higginbotham*, 495 F. 3d at 759 (“The securities laws do not require firms to ‘disclose’ information that is already in the public domain.”). Accordingly, Plaintiff’s claims based on these alleged omissions must be dismissed.

IV. ANY ALLEGED MISREPRESENTATIONS WERE NOT FALSE OR MISLEADING.

While the overwhelming majority of the allegations in FAC are based on alleged omissions, Plaintiff seems to suggest, although far from clear given its shotgun pleading, that three statements themselves were false and misleading: Leasure’s statement that the Company intended to “eventually brand everything under the Inotiv name” (¶¶ 201-202(c)); Wilbourn’s statements regarding the improvements made to the flooring at the Cumberland Facility (¶¶ 210, 214(e)); and Wilbourn’s statement that the “temporary lapse in providing the level of care” at the Cumberland

²¹ Additionally, Plaintiff lacks standing to pursue claims based on statements made after May 26, 2022—the date Plaintiff last purchased Inotiv stock (ECF No. 53-1 Ex. A)—including statements during the August 10, 2022 earnings call addressing NHP supply (¶¶ 231-33), and in the August 12, 2022 Form 10-Q addressing the subpoenas (¶¶ 234-36). These “post-purchase statements cannot form the basis of Rule 10b-5 liability, because the statements could not have affected the price at which plaintiff actually purchased.” *Roots P’ship v. Lands’ End, Inc.*, 965 F.2d 1411, 1420 (7th Cir. 1992); *see also Davis v. SPSS, Inc.*, 385 F. Supp. 2d 697, 705-06 (N.D. Ill. 2005) (compiling cases dismissing securities fraud claims based on post-purchase statements).

Facility was “caused by COVID” (¶¶ 209, 215). Yet, none of these claims are supported by plausible, let alone particularized, factual allegations demonstrating that the statements were false or misleading when made. *See In re Guidant Corp. Sec. Litig.*, 536 F. Supp. 2d 913, 926 (S.D. Ind. 2008), *aff’d sub nom. Fannon v. Guidant Corp.*, 583 F.3d 995 (7th Cir. 2009) (citing 15 U.S.C. § 78u-4(b)(1)).

First, Plaintiff claims that Leasure’s statement regarding branding was false and misleading because Inotiv “appears to have taken no steps to” rebrand since the statement was made. (¶ 202(c)). This speculative allegation, however, does not demonstrate that the statement was false or misleading when made. Additionally, as noted below, Leasure’s representation is a forward-looking statement protected by the safe harbor.²² Second, Plaintiff alleges that Wilbourn’s statements regarding the improvements to flooring were false and misleading because USDA inspectors found repeat flooring violations during the March 2022 inspection. (¶ 214(e)). This too is insufficient. Wilbourn did not state or imply that the flooring violations had been fully remediated.²³ In fact, Wilbourn stated that the “boarding” used to address the problems with “gaps in flooring” was “a short-term mitigation effort.” (Ex. R at 10). Wilbourn further noted that some improvements to flooring had not yet been made, stating that Envigo was “ready to place an order [in] mid-February” to finish changing the “galvanized chain-link to stainless steel.” (¶ 210). Finally, Wilbourn’s statement that the COVID-19 pandemic contributed to the issues at the Cumberland Facility is not contradicted by CW4’s belief “that high turnover of employees

²² Moreover, Plaintiff fails to allege any sort of causation with respect to this statement.

²³ Wilbourn further explained that “corrective actions take some time and several months to implement.” (¶ 210). Additionally, Plaintiff attempts to plead fraud by hindsight by relying on the March 2022 inspection, which did not take place until “approximately one month after the Virginia Senate Hearing.” (*Id.*); *see Zerger v. Midway Games, Inc.*, No. 07 C 3797, 2009 WL 3380653, at *7 (N.D. Ill. Oct. 19, 2009) (a plaintiff must allege “facts contemporaneous to the statements” showing that they were false).

contributed to the problems.” (¶¶ 144, 215).²⁴ That conclusion is nonsensical. Further, Wilbourn, in fact, acknowledged retention issues, stating that Envigo was implementing “retention initiatives,” including increased salaries for new and current employees. (Ex. R at 5). Accordingly, Plaintiff fails to allege an actionable misrepresentation.

V. IN ANY EVENT, NEITHER THE ALLEGED OMISSIONS NOR ANY PURPORTED MISREPRESENTATIONS WERE MATERIAL.

Plaintiff cannot plausibly allege that many of the statements or omissions at issue are actionable for the additional reason that they constitute puffery or non-actionable opinions, are otherwise immaterial as a matter of law, or are protected by the PSLRA safe harbor.

A. The Qualitative Statements at Issue Are Immaterial Puffery and Non-Actionable Statements of Opinion.

Many of the statements challenged by Plaintiff fail for the additional reason that they constitute puffery or statements of opinion. “[P]uffery and optimistic rhetoric generally cannot provide a basis for a securities fraud action.” *In re Guidant Corp. Sec. Litig.*, 536 F. Supp. 2d at 928; *see also Eisenstadt v. Centel Corp.*, 113 F.3d 738, 746 (7th Cir. 1997) (“Mere sales puffery is not actionable under Rule 10b-5.”). “Puffery includes (1) indefinite predictions of growth; (2) optimistic rhetoric and hype; (3) subjective statements; and (4) vague statements.” *Chandler v. Ulta Beauty, Inc.*, 18-CV-1577, 2022 WL 952441, at *7 (N.D. Ill. Mar. 30, 2022). Virtually all of the challenged statements about the quality and scope of Envigo’s and OBRC’s business²⁵ are textbook puffery.

²⁴ This allegation also fails to state a claim because the CW statements fail to allege falsity, as discussed above.

²⁵ Such statements include those made in the September 21, 2021 investor presentation (¶¶ 162-67), the October 5, 2021 Proxy Statement (¶¶ 173, 175-76), the November 5, 2021 Form 8-K announcing the Envigo merger (¶ 181), the NHP fact sheet (¶¶ 186-89), the November 11, 2021 statement on PETA report (¶ 193), the November 16, 2021 statement on USDA inspections (¶ 197), the November 16, 2021 presentation to the Jeffries London Healthcare Virtual Conference (¶ 200), the January 27, 2022 Form 8-K announcing the

For example, statements such as: Envigo’s “dedication to quality” made it an “excellent cultural fit for Inotiv” (¶ 163); “Envigo expends significant resources on compliance efforts” (¶ 175); “high degree of focus on animal welfare” (¶ 176); “high-quality small and large research models” (¶ 181); “the world’s largest and most trusted sources of NHPs” (¶ 187); “high-quality breeding farm partners” (¶ 188); “procure high-quality nonhuman primates” (¶ 189); “highest quality of animal welfare is a core value” (¶ 193); Envigo acquisition was “transformative” (¶ 200); “a leader in primate welfare and supply . . . client needs are met with the highest level of animal welfare” (¶ 204); “commitment to the highest animal welfare standards” (¶ 207); and “great condition of the dogs” (¶ 210) are immaterial puffery and are not actionable as a matter of law. *See Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199, 232 (S.D.N.Y. 2018) (“committed to serving safe, high quality food to [its] customers and that its food safety programs are also designed to ensure that [the Company] compl[ies] with applicable federal, state and local food safety regulations—[wa]s inactionable puffery.”).²⁶

In addition, many of these statements, as well as others are non-actionable statements of opinion. “An opinion is ‘a belief[,] a view,’ or a ‘sentiment which the mind forms of persons or things.’” *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 183 (2015). Here, opinion statements in the FAC include we “see Envigo as a best-in-class provider of high-quality research models and services” (¶ 163); “[m]any of these allegations we know to be misleading and lacking important context” (¶ 193-94); “[Envigo] would add significant value to

OBRC acquisition (¶ 204), the February 3, 2022 congressional testimony (¶ 207), and the Q1 2022 Form 10-Q (¶ 218).

²⁶ See also *Employees’ Ret. Sys. v. Whole Foods Mkt., Inc.*, 905 F.3d 892, 902 (5th Cir. 2018) (generalized statements about a company’s “transparency, quality, and responsibility” were puffery); *In re Stratasys Ltd. S’holder Sec. Litig.*, 864 F.3d 879, 882 (8th Cir. 2017) (statements that products offer “unmatched speed, reliability, quality and connectivity” are vague and nonverifiable).

us” (¶ 201); “we were deeply disappointed in the results of our USDA inspection” and was “working hard to fix the current issues and [has] already taken many steps towards doing so” (¶ 208); “we acted swiftly” (¶ 210); “showed improvement” (*id.*); and “I think we’ve done a very nice job of filling some of these roles” (¶ 225). To allege that a statement of opinion is actionable, a plaintiff must allege both that “the speaker did not hold the belief she professed” and that the belief is objectively untrue. *Omnicare, Inc.*, 575 U.S. 175, 185-86; *see also Fryman v. Atlas Fin. Holdings, Inc.*, 462 F. Supp. 3d 888, 897-901 (N.D. Ill. 2020) (applying *Omnicare* to § 10(b) claims). Plaintiff does not even attempt to allege facts to satisfy the *Omnicare* standard. Absent such allegations, these statements fail to support a claim.²⁷ As such, these statements must be dismissed for the additional reason that they are non-actionable opinions.

B. Revenue from the Cumberland Facility Was Financially Immaterial.

To state a claim for securities fraud, Plaintiff must allege a material misrepresentation or omission. However, information regarding the Cumberland Facility was not financially or otherwise material and Plaintiff does not allege otherwise. The Cumberland Facility was just one facility of 22 in the RMS segment, comprised less than ***one percent*** of Inotiv’s total revenue, and was not profitable. (¶¶ 45, 261; Ex. M at 4); *see Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995) (holding that two FDA inspections finding deficiencies in manufacturing plant were not material because the plant was only one of over thirty locations and produced only 10 of the 1,000 products that the company manufactured); *Higginbotham*, 495 F.3d at 759 (discussing 5%

²⁷ See, e.g., *Conagra*, 495 F. Supp. 3d at 649 (defendant’s statements that acquired company’s portfolio was “complementary,” “very strong,” and “growing” were inactionable opinions); *Société Générale*, 2018 WL 4616356, at *5 (statements that defendant was “complying with the law” and “cooperating with the government’s investigation” were statements of opinion when viewed in context of accompanying disclosures regarding IRS investigation and grand jury subpoena); *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1323 (11th Cir. 2019) (statement that defendant expected “the next round of results from [independent] monitor to show that we have made progress in improving our internal testing and compliance monitoring” was a statement of opinion).

change as rule of thumb for materiality and noting that “[r]easonable executives need not see a 1.5% change [in profit] as substantial”); *In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 29 (1st Cir. 2012) (“an undisclosed speculative chance of an event that affects only a very small proportion of revenues is not material.”). Investor commentary confirms that the market did not view the Cumberland Facility as material to an investment in the Company. When Inotiv announced that it would close the facility, one analyst commented that the decision “should be well-received by investors,” as closing was more financially beneficial than keeping it open, given the cost of needed improvements. (¶ 263).²⁸

C. Defendants’ Forward-Looking Statements Are Protected by the Safe Harbor.

Plaintiff’s attacks on Inotiv’s statements (1) in the November 5, 2021 and January 27, 2022 8-Ks and during the Q2 2022 earnings call regarding future benefits of the Envigo and OBRC acquisitions; and (2) during the Jefferies Healthcare Conference regarding the Company’s intent to “eventually” rebrand everything under the Inotiv name also fail because the statements are protected by the PSLRA safe harbor and Plaintiff has not alleged actual knowledge of falsity. A company cannot be liable under § 10(b) if it either (1) makes forward-looking statements that are identified as such and are accompanied by “meaningful cautionary statements” or (2) makes forward-looking statements without “actual knowledge” that the statements were false or

²⁸ The fact that “Envigo supplied approximately 25% of research beagles to the market” does not mean that revenue from the Cumberland Facility was material to Inotiv or a reasonable investor, which Plaintiff does not and cannot allege. (*See* ¶ 311d). For this reason, *Shah v. Zimmer Biomet Holdings, Inc.*, 348 F. Supp. 3d 821 (N.D. Ind. 2018), stands in stark contrast to this case. There, the plaintiffs alleged that the defendant company was aware of significant audit findings for one of its key facilities that “were completely anathema to the growth and success” the company was simultaneously telegraphing to the market because it could not meet those goals without the facility operating at full capacity. *Id.* at 838. Indeed, when the company was ultimately forced to shut down the facility to remediate the issues, it missed its revenue and growth goals by 20%. *Id.* The same cannot be said here. As noted, the closure of the Cumberland Facility had absolutely no adverse financial impact.

misleading. 15 U.S.C. § 78u-5(c)(1); *Stavros v. Exelon Corp.*, 266 F. Supp. 2d 833, 842-43 (N.D. Ill. 2003).

First, the statements cited in the FAC regarding the future benefits of the Envigo and OBRC acquisitions and the Company’s intent to “eventually” rebrand used clear, forward looking language and were identified as forward-looking statements.²⁹ The accompanying disclosures further stated that “[s]uch statements involve risks,” including “the possibility that expected benefits may not materialize as expected . . . and other risks that are described in the Company’s latest [] Form 10-K and its other filings with the SEC.” (Ex. H at 6; *see also* Ex. F at 11; Ex. Q at 10, Ex. S at 4). In turn, the Company’s 2021 Form 10-K, filed December 21, 2021, as well as other SEC filings, included various meaningful disclosures surrounding acquisition and integration risks, as well as the limited supply of NHPs, as discussed above. Such detailed cautionary statements qualify for protection under the PSLRA’s safe harbor. *See St. Lucie Cnty. Fire Dist. Firefighters’ Pension Tr. Fund v. Motorola, Inc.*, 10 C 427, 2011 WL 814932, at *9 (N.D. Ill. Feb. 28, 2011); *Stavros*, 266 F. Supp. 2d at 843 (considering warnings in SEC filings that were incorporated by reference).

Second, as explained in Section VI below, Plaintiff has failed to plead recklessness, let alone that any Defendant had “actual knowledge” of falsity, as required to state a claim based on a forward looking statement. 15 U.S.C. § 78u-5(c)(1)(B)(i); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 530 (S.D.N.Y. 2015), *aff’d sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). As such, Defendants’ forward-looking statements must be dismissed.

²⁹ See ¶ 181 (“**will receive**”); ¶ 201 (“**eventually** brand everything under the Inotiv name”); ¶ 204, January 27, 2022 Press Release (“**will accelerate** growth . . .” and “**will provide** increased access”); ¶ 224 (“**we anticipate** supporting growth . . . and consolidating”); *see also* Ex. H at 6; Ex. Q at 10; Ex. S at 4 (noting that forward-looking statements may contain similar words such as “will”).

VI. PLAINTIFF DOES NOT PLEAD A COGENT OR COMPELLING INFERENCE OF SCIENTER.

Plaintiff's § 10(b) claim fails for the independent reason that the FAC fails to adequately plead scienter. To do so, Plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *See* 15 U.S.C. § 78u-4(b)(1)-(2). A strong inference is one that is "powerful or cogent" when weighed against "plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 323-24. Plaintiff's § 10(b) claim may only survive "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* The required state of mind is knowledge or, at the very least, a showing of recklessness, defined as "an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 673 F. Supp. 2d 718, 745 (S.D. Ind. 2009), *aff'd*, 679 F.3d 952 (7th Cir. 2012).

Wholly absent from the FAC are the type of detailed scienter allegations demanded by Tellabs. For example, there is not a single damning internal report, suspicious stock sale by an insider, or first-hand knowledge of the alleged fraud. In fact, rather than selling any of their shares, Leasure, Taylor, and Sagartz each purchased additional stock in the Company during the class period. (Ex. J at 1-3). These purchases weigh heavily against an inference of scienter. *See Conagra*, 495 F. Supp. 3d at 666-67 (finding that purchases of stock combined with a lack of sales weigh against the possibility of a strong inference of scienter); *In re Supreme Indus., Inc. Sec. Litig.*, 3:17-CV-143-PPS/MGG, 2018 WL 2364931, at *11 (N.D. Ind. May 23, 2018) (finding that defendants' retention of large amounts of their shares undermined the inference of scienter). Plaintiff's generalized allegations, unsupported and speculative inferences, and vague claims from

unnamed former employees who had no relevant contact with company insiders are simply not enough. Each one of Plaintiff's scienter theories fails as a matter of law.

A. Plaintiff's CW Allegations Do Not Create a Powerful Inference of Scienter.

The four CWs offer nothing more than confirmations that certain Inotiv executives visited Envigo and OBRC facilities as part of due diligence and unsupported speculation that they would have been aware of the purported conditions at the Cumberland Facility and the grand jury subpoenas. (¶¶ 121-145, 243; *see* Section II). As a result, the FAC's CW allegations fall well short of establishing a strong inference of scienter.³⁰

As discussed above, none of the CWs are alleged to have had relevant interactions with any of the Individual Defendants, and their anecdotal allegations do not coincide with the statements at issue. For example, CW1 and CW3's observations that conditions at the Cumberland Facility³¹ were poor and "impossible to miss" and the USAO-SDF investigation into importation of NHPs was "general knowledge" and a topic of discussion among Envigo management are wholly insufficient.³² (¶¶ 122, 127-28, 142, 178, 243); *Zimmer*, 673 F. Supp. 2d at 747 ("Plaintiff must allege actual knowledge by the defendant, not some second-hand belief that such knowledge existed"); *In re Bally Total Fitness Sec. Litig.*, No. 04-cv-03530, 2006 WL 3714708, at *9 (N.D. Ill. July 12, 2006) (characterizing "must have known" allegations as "an end-run around the requirement that plaintiffs set forth particularized facts to suggest that defendants acted knowingly or recklessly"); *Roth v. OfficeMax, Inc.*, 527 F. Supp. 2d 791, 801 (N.D. Ill. 2007) (dismissing

³⁰ Moreover, CW allegations must be "discounted." *Higginbotham*, 495 F.3d at 756 ("Perhaps these confidential sources have axes to grind. Perhaps they are lying. Perhaps they don't even exist.").

³¹ CW1 and CW3 do not even attempt to allege that they had personal knowledge of conditions at the Cumberland Facility.

³² The allegation that receipt of a subpoena was somehow apparent upon visiting a facility further defies common sense.

“must have known” and “should have known” allegations); *Conagra*, 495 F. Supp. 3d at 659 (“particularized facts are especially important in the merger context, in which a company may have less than complete access to information prior to a deal’s close”). Further, “mere access to information,” which is all the CWs allege, *at most*, fails to satisfy the PSLRA. *See Cornelsen v. Infinium Cap. Mgmt., LLC*, 916 F.3d 589, 602 (7th Cir. 2019) (“conclusory allegations of scienter derived from a defendant’s mere access to information” fail to satisfy the PSLRA); *see also In re Supreme Indus.*, 2019 WL 1436022, at *5 (alleging that defendants had access to greater detail than was publicly disclosed is insufficient, even when defendants knew the information was important).

Tellingly, the FAC contains no allegations indicating that Defendants attempted to conceal conditions at the Cumberland Facility or the grand jury subpoenas. To the contrary, Plaintiff alleges that CW2 stated that Envigo’s leadership sent an internal communication to employees after the July inspection indicating that “there would be an internal inquiry and a town hall meeting on the subject.” (¶ 132). If Defendants were attempting to conceal the USDA inspection or findings from investors, they presumably would not have notified employees or presented them with “an opportunity to ask questions and receive answers from management.” (*Id.*) Similarly, CW1’s allegation that “Tucker [was] not be continuing in his position with OBRC after the Inotiv acquisition, at least in part due to the [criminal matter]” is inconsistent with any notion that Inotiv condoned his actions or turned a blind eye to misconduct. (¶ 128).

Finally, Plaintiff does not, because it cannot, allege that Defendants (or anyone else) knew that the June 2021 subpoenas would result in legal action against a supplier over a year later, after an indictment was unsealed, or cause further disruption to the supply of NHPs. (*See* ¶ 227); *City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1260 (10th Cir. 2001) (federal securities

laws do not provide a cause of action for failing to foresee future events). Similarly, the FAC offers no particularized facts to support the conclusion that Defendants knew, or should have known prior to the indictment, that its principal NHP supplier was the subject of the federal investigation, particularly given that subpoenas were also sent to Inotiv's competitors. (*See ¶ 230*).³³ In short, Plaintiff's confidential witness allegations do not come close to alleging a strong inference of scienter and, in fact, cut against any inference.

B. The Small Size of the Cumberland Facility Cuts Against an Inference of Scienter and Cannot Support a “Core Operations” Argument.

Plaintiff next alleges that due to “the importance of operations at the Cumberland Facility,” Leasure, Taylor, and Sagartz must have known that Inotiv’s representations about it were false or misleading. (¶¶ 244-46). To rely on the core operations theory, Plaintiff must demonstrate that the subject of presumed knowledge was critical to the company’s core operations. *See Zimmer*, 673 F. Supp. 2d at 746. In a typical case, “senior positions” within a company “do not suggest scienter without additional support from internal documents or communications.” *Société Générale*, 2018 WL 4616356, at *8. Plaintiff has not made the required showing here. To the contrary, as discussed above, the Cumberland Facility comprised only about 1% of Inotiv’s total revenue and was a net loss for the Company. (Ex. M at 4).³⁴ Rather than supporting an inference of scienter, the “small scale” of the facility “strongly weighs against an inference of scienter.” *Zimmer*, 673 F. Supp. 2d

³³ Inotiv’s timely disclosures and robust risk factors also cut against any inference of scienter. *See Zimmer*, 673 F. Supp. 2d at 749 (“The inference against scienter becomes even more ‘cogent and . . . compelling’ given the fact that Defendants made a timely disclosure”).

³⁴ The fact that the RMS segment, as a whole, accounts for approximately three quarters of revenue (¶ 244) does not mean that Defendants must have had detailed knowledge of the grand jury subpoenas or the Cumberland Facility, which was just one facility of 22 in the RMS segment. Plaintiff similarly fails to explain how the fact that Leasure, Taylor, and Sagartz “represented the Company during investor conference calls” (¶ 246) somehow implies that they would have detailed knowledge of the grand jury subpoenas or the Cumberland Facility. The FAC does not contain any other allegations that could support a core operations theory with respect to the grand jury subpoenas.

at 748–49 (the fact that products at issue “accounted for a mere six percent of [defendant’s] worldwide business” strongly cut against inference of scienter); *Stavros*, 266 F. Supp. 2d at 851 (dismissing claims based on alleged GAAP violation that allegedly inflated reported earnings by less than three percent). Put differently, Defendants had no reason to lie about the Cumberland Facility’s compliance or viability, given its small size. This is confirmed by the fact that analysts ultimately reacted positively to the news that the Company was closing the facility. (Ex. V at 1). Accordingly, Plaintiff’s core operations theory fails.

In sum, “assess[ing] all the allegations holistically,” as required under *Tellabs*, Plaintiff utterly fails to meet the “demanding” requirements to allege scienter under the PSLRA.³⁵ *Tellabs*, 551 U.S. at 326. There are absolutely no “facts indicating that Defendants were actually aware of some serious problem.” *Zimmer*, 673 F. Supp. 2d at 747. None of the CWs had relevant interactions with Defendants and Plaintiff’s core operations argument fails—the Cumberland Facility was not a “core operation.” On the other hand, as set forth above, multiple facts cut directly against an inference of scienter, including that three of the four Individual Defendants *purchased* stock in the Company during the class period and none of them sold any stock; Inotiv made timely disclosures, warned investors of the relevant risks, and sent internal communications to employees about the Cumberland Facility; and Defendants had no reason to conceal conditions at the facility given its small size and unprofitability. Plaintiff’s § 10(b) claim can and should be dismissed for this reason alone.

³⁵ Plaintiff’s throwaway allegation that the retirement of Envigo’s Chief Operating Officer was “abrupt” (¶ 247) is also utterly lacking in the particularized facts required under *Tellabs*. Similarly, the fact that Envigo maintained its name and branding after the acquisition (¶ 248), which is commonplace, cannot possibly have had concealed anything, particularly given Inotiv’s various disclosures about the merger and the fact that investors voted on matters to effectuate the merger.

VII. PLAINTIFF FAILS TO ALLEGE LOSS CAUSATION IN SUPPORT OF ITS § 10(B) CLAIM.

To plead loss causation, a plaintiff must show (1) that the defendant's alleged misrepresentations artificially inflated its stock price, and (2) that the stock's value deteriorated "once the market learned of the deception." *Ray v. Citigroup Global Mkts., Inc.*, 482 F.3d 991, 995 (7th Cir. 2007). To do so, the complaint must identify one or more "corrective disclosures" that "relate back" to the alleged misrepresentations or omissions and revealed new information to the market demonstrating that the company's previous statements were false. *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 175 (2d Cir. 2005); *Meyer v. Greene*, 710 F.3d 1189, 1197-98 (11th Cir. 2013). "[T]here must be 'a causal connection between the material misrepresentation and the loss,' not simply that the misrepresentation 'touches upon' a later economic loss." *Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 843 (7th Cir. 2007). Here, Plaintiff alleges five "partial" corrective disclosures from November 15, 2021 to November 17, 2022, none of which relate back to prior statements or otherwise demonstrate that the market reacted to the disclosure of alleged fraud. (¶¶ 259-64).

The first purported corrective disclosure occurred on November 15, 2021, when the USDA posted reports from the July 2021 inspection on its website. (¶ 260). Plaintiff alleges that PETA issued a press release including links to the reports and that Inotiv's stock price fell from \$55.55 on November 12, 2021, by \$2.80 per share, or approximately 5%, to close at \$52.75 on November 15, 2021. (*Id.*). However, Inotiv's stock price quickly rebounded the following day to close at \$54.92. Further, just four days after the temporary drop, Inotiv's share price closed as high as \$57.88, undercutting any allegation that disclosure of the USDA reports "caused any material drop in the stock price." See *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1198 (9th Cir. 2021) (affirming dismissal for failure to allege loss causation because quick and sustained price recovery after modest stock drop refuted inference that information allegedly concealed caused any material

drop); *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005) (loss causation requires allegation “that [the company]’s share price fell significantly after the truth became known”); *Wade v. WellPoint, Inc.*, 892 F. Supp. 2d 1102, 1136 (S.D. Ind. 2012) (where stock price rebounded days later plaintiff failed to link corrective disclosure to any meaningful dip in stock price).³⁶ Accordingly, Plaintiff’s first corrective disclosure fails as a matter of law.

The second alleged corrective disclosure is February 16, 2022, when Inotiv filed its Q1 2022 Form 10-Q. Plaintiff alleges this 10-Q disclosed details of the USDA’s inspection “for the first time.” (¶ 261). However, Plaintiff fails to acknowledge—presumably because it does not fit with its theory of loss causation—that Inotiv’s December 21, 2021 Form 10-K included a nearly identical risk disclosure regarding the USDA inspections and Inotiv’s stock only traded higher following the announcement. (Ex. G at 7; Ex. X at 3). The USDA reports were also made public months earlier. (¶¶ 196, 210). Similarly, the disclosure in the Q1 2022 10-Q that Envigo received and was responding to a grand jury subpoena relating to the importation of NHPs did not relate back or otherwise reveal fraud. (¶ 261). Further, as Plaintiff points out, the USAO-SDF investigation was public as early as June 2021. (¶¶ 112-14). A corrective disclosure must “present facts to the market that are new, that is, publicly revealed for the first time”—the Q1 2022 Form 10-Q did not do so. *See Meyer*, 710 F.3d at 1197-98; *In re Omnicom Grp, Inc. Sec. Litig.*, 597 F.3d

³⁶ Additionally, Plaintiff alleges that purported conditions at the Cumberland Facility were publicized prior to and during the class period. (¶¶ 146-152, 193; *see* Section I, B). Further, on November 11, 2021, Inotiv disclosed that Envigo had two separate USDA inspections at its Cumberland site and was “incorporating the feedback” from those inspections. (¶ 193). However, the market did not react negatively to this information. Rather, Inotiv’s stock price closed at \$55.55 on November 12, 2021—the highest closing price since the beginning of the class period—undermining Plaintiff’s theory of loss causation. (Ex. X at 2); *see Dura*, 544 U.S. at 347.

501, 511 (2d Cir. 2010) (disclosure did not constitute a corrective disclosure of fraud because information was known to the market a year before).³⁷

The third purported corrective disclosure is the Company's May 20, 2022 Form 8-K announcing that the DOJ had executed a search warrant at the Cumberland Facility on May 18, 2022, and filed a civil complaint against Envigo the following day alleging violations of the AWA. (¶ 262). Thereafter, the court issued the TRO requested by the government on May 21, 2022. (*Id.*). Plaintiff alleges that Inotiv's stock price fell as a result on May 23, 2022. (*Id.*). However, Plaintiff fails to connect this stock drop to any purported disclosure of fraud, rather than market reaction to the fact that a search warrant was exercised and a case was filed against Envigo.³⁸ *Dura*, 544 U.S. at 343 (plaintiff must distinguish alleged fraud from the “tangle of [other] factors” that affect a stock’s price); *Sapssov v. Health Mgmt. Assocs., Inc.*, 22 F. Supp. 3d 1210, 1231 (M.D. Fla. 2014), *aff'd*, 608 F. App'x 855 (11th Cir. 2015) (“[N]ot every bit of bad news that has a negative effect on the price of a security necessarily has a corrective effect for purposes of loss causation.”). Accordingly, this disclosure is also insufficient to allege loss causation.

The fourth alleged corrective disclosure is the Company's June 13, 2022 Form 8-K announcing that it would close the Cumberland Facility, rather than make the required improvements, which had gotten more expensive. In response, Plaintiff alleges that Inotiv's stock

³⁷ Analyst commentary on this 10-Q further demonstrates that the market was not reacting to the disclosure of fraud. See *In re IMAX Sec. Litig.*, 272 F.R.D. 138, 149 (S.D.N.Y. 2010) (analyst reports were evidence of “the market’s understanding” of alleged corrective disclosure). Lake Street noted that “shares have traded in an inverse direction to our expectations” and suggests five *potential* matters that “could explain the move.” (Ex. U. at 1). Similarly, Craig-Hallum Capital Group LLC reported that it was “surprised by the price action” and “one of the biggest questions [they had] received from investors is, ‘[w]hy is the stock down?’” (Ex. T at 1).

³⁸ Any argument that the DOJ actions revealed previously undisclosed conditions or violations cannot stand in light of Plaintiff’s assertion that the DOJ action reported conditions “that were consistent with, if not substantially identical to, the reports of USDA inspections carried out prior to and during the Class Period,” which were previously disclosed. (See ¶ 101).

price dropped a mere \$0.25 or less than 2%—from \$13.03 to \$12.78. (¶ 263; Ex. X at 8). Even if less such an immaterial stock drop could somehow constitute a “significant” one under *Dura*, the price rebounded to \$13.10 the following day, June 15, 2022, undercutting Plaintiff’s assertion that the market was reacting to some revelation of fraud. (Ex. X at 8); *Dura*, 544 U.S. at 347; *Wochos*, 985 F.3d at 1198; *Omnicom*, 541 F. Supp. 2d at 552 (“[a] decision to reverse course, particularly in a dynamic business environment, does not imply that the earlier business strategy was a subterfuge”). Further, analysts reported that the decision to close the Cumberland Facility was “well-received by investors”—not somehow viewed as a disclosure of fraud. (¶ 263; *see also* Ex. V at 1). Again, this alleged corrective disclosure fails to support a claim.

The fifth and final alleged corrective disclosure is the Company’s November 17, 2022 statement that it had become aware that the USAO-SDF had filed criminal charges in connection with the importation of NHPs. (¶ 264). Again, Plaintiff fails to connect this disclosure to any prior misstatements. Conversely, as Plaintiff admits, the market reacted to the potential that the recently unsealed indictment “could disrupt Inotiv’s supply of primates,” not to the disclosure of fraud. (*Id.*; *see also* Ex. W at 1-2 (downgrading as a result of “uncertainty around the future of the Company’s largest NHP supplier” and noting that they did not believe Inotiv or OBRC were at fault)); *see also* *Sapssov*, 22 F. Supp. 3d at 1231. Accordingly, Plaintiff’s loss causation allegations fail with respect to the November 2022 disclosure as well.

Finally, Plaintiff conveniently omits that Inotiv’s stock price *rose* following its May 16, 2022 disclosure of the subpoena to OBRC. (Ex. X at 7). Accordingly, Plaintiff has not and cannot allege loss causation in connection with the purported omission of the OBRC subpoena. *See Dura*, 544 U.S. at 347. In sum, the FAC fails to adequately allege a single corrective disclosure that satisfies the applicable pleading standard. Plaintiff’s § 10(b) claim must be dismissed.

VIII. PLAINTIFF'S § 14(A) CLAIM ALSO FAILS.

Plaintiff also fails to allege an actionable misstatement or omission or loss causation to support its § 14(a) claim. Plaintiff contends that statements in the September 21, 2021 investor presentation, the Merger Agreement, and the October 2021 Proxy were false and misleading because they failed to disclose: purported USDA violations found at the Cumberland Facility during the July and October 2021 inspections and that Envigo was producing documents in response to a grand jury subpoena. (¶¶ 309-311). However, omission of information from a proxy statement will violate § 14(a) only if either “the SEC regulations specifically require disclosure of the omitted information in a proxy statement, or the omission makes other statements in the proxy statement materially false or misleading.”” *Orlando v. CFS Bancorp, Inc.*, No. 2:13-CV-261 JD, 2013 WL 5797624, at *4 (N.D. Ind. Oct. 28, 2013). Plaintiff makes no allegations that such information was required to be disclosed under SEC proxy rules and none of the challenged statements were rendered false or misleading as a result of the purported omissions, as set forth above. (*See* Section I, III). Additionally, as noted above, the allegedly omitted information was not material and many of the challenged statements constitute immaterial puffery. (*See* Section V).

Further, “[t]o plead loss causation, a Section 14(a) plaintiff must plead both economic loss and proximate causation.” *Kuebler*, 13 F.4th at 645. Plaintiff’s allegations that shareholders “were caused to approve the acquisition of Envigo for more than the true value of Envigo” and suffered economic losses measured by “the difference between the value Inotiv shareholders received and Envigo’s true value at the time of the acquisition” are not sufficient. (¶¶ 318-19).³⁹ Courts across

³⁹ Plaintiff fails to allege any facts to support its conclusory claim that Envigo was overvalued as a result of the alleged omissions regarding the Cumberland Facility and the NHP investigation. *See Kuebler v. Vectren Corp.*, 412 F. Supp. 3d 1000, 1011 (S.D. Ind. 2019), *aff'd*, 13 F.4th 631 (7th Cir. 2021) (dismissing claim where allegations were “too attenuated to support a causal link between the omitted [information] and purported damages”). Oppositely, the FAC alleges that the Board took the due diligence review into account when deciding whether to approve the merger and, presumably, the purchase price. (¶¶ 174, 178).

the country have consistently rejected similar allegations. *See Trahan v. Interactive Intel. Grp., Inc.*, 308 F. Supp. 3d 977, 1000 (S.D. Ind. 2018) (allegation that plaintiff was damaged by proxy misstatements “in the amount of ‘the difference between the price [] shareholders received and [acquired company’s] true value at the time of [the merger]’” was speculative and insufficient to support § 14(a) claim).⁴⁰ Plaintiff’s 14(a) claim should be dismissed for the additional reason that the FAC fails to plead loss causation.

IX. PLAINTIFF’S § 20(A) CLAIMS ALSO FAIL.

Lastly, Plaintiff’s § 20(a) claims are predicated on violations of § 10(b) and § 14(a). Because Plaintiff has failed to adequately plead its § 10(b) and § 14(a) claims, its § 20(a) claims must also be dismissed. *See Pugh v. Trib. Co.*, 521 F.3d 686, 693 (7th Cir. 2008).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the FAC in its entirety with prejudice.

Dated: January 27, 2023

Respectfully submitted,

/s/ Michael J. Diver

Lead Counsel for Defendants

Further, to the extent Plaintiff is relying on its stock drop allegations to allege loss causation in support of its § 14(a) claim (*see ¶ 313*), those allegations fail for the same reasons set forth above (*see Section VII*).

⁴⁰ See also *In re Resolute Energy Corp. Sec. Litig.*, No. CV 19-77-RGA, 2021 WL 327385, at *4 (D. Del. Feb. 1, 2021), aff’d, No. 21-1412, 2022 WL 260059 (3d Cir. Jan. 27, 2022) (plaintiff could not allege loss causation “simply by alleging that [defendant’s] stock was undervalued at the time of the merger”); *In re GTx S’holders Litig.*, No. 19 CIV. 3239 (AT), 2020 WL 3439356, at *5 (S.D.N.Y. June 23, 2020) (rejecting theory that “had the [c]ompany remained independent, [it] would have achieved a hypothetically higher stock value”); *Gray v. Wesco Aircraft Holdings, Inc.*, 847 F. App’x 35, 36 (2d Cir. 2021) (allegation that shareholders suffered a loss based on the difference between the merger consideration and the intrinsic fair value of the shares was speculative); *In re Ocera Therapeutics, Inc. Sec. Litig.*, No. 17-CV-06687-RS, 2018 WL 7019481, *11 (N.D. Cal. Oct. 16, 2018), aff’d, 806 F. App’x 603 (9th Cir. 2020) (dismissing allegation that losses amounted to “the difference between the price [] stockholders received and the ‘true value’ of their shares”); *In re Tangoe, Inc. S’holders Litig.*, 333 F. Supp. 3d 77, 109 (D. Conn. 2018) (dismissing allegation that “shares would have been more valuable if it remained a standalone company”).

CERTIFICATE OF SERVICE

I certify that on this 27th day of January, 2023, a true and correct copy of the foregoing document was served on all counsel of record through the Court's CM/ECF system.

/s/ Michael J. Diver